

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Serial Number : 10/518,223
Filing Date : 15 Dec 2004
In re Appl. of : Cheng, Ning Man *et al.*
Art Unit : 1652
Examiner : Dr. I. H. Chowdhury
Attorney Docket : B001.001.NPRUS

DECLARATION UNDER 37 C.F.R. §1.131

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir/Madam,

We, Ning Man Cheng, Yun Chung Leung and Wai Hung Lo, (collectively, “the Applicants”) do declare and state as follows:

1. We are joint inventors of the subject matter which is described and now claimed in the above-identified application.

2. This declaration and its attachments were prepared to evidence reduction to practice of the invention of at least claim 28 of the above-identified application (*i.e.*, USSN 10/518,223), on a date before January 25, 2002, which is the earliest effective filing date of Tepic *et al.*, WO 03/063780 (PCT/US03/02342). Tepic *et al.* was cited by the Examiner in an Office Action dated July 27, 2007, as prior art to the instant application pursuant to 35 U.S.C. §102(e).

3. The invention described in claim 28 of the above-identified application was completed by us or under our supervision prior to January 25th, 2002 as documented in the laboratory notebook records (Exhibit A through Exhibit D) filed herewith. These activities, among

other activities, were carried out in Hong Kong, China, which has been a member of the World Trade Organization since January 1, 1995.

EVIDENTIARY EVIDENCE

4. Exhibit A shows laboratory records documenting the existence of a treatment protocol prior to the critical date that was used to administer a modified, full-length recombinant human arginase I polypeptide which was covalently linked to at least one polyethylene glycol (PEG) molecule to a human subject with rectal cancer as detailed in the specification of the instant application in Example 9A and Example 12. (see US 2005/0244398).

5. Exhibits B, C and D document that prior to the critical date, the Applicants had administered a modified, full-length recombinant human arginase I polypeptide according to the protocol of Exhibit A, which was covalently linked to at least one polyethylene glycol (PEG) molecule in a method to treat a malignancy (rectal cancer) in a human subject. These laboratory records document that prior to the critical date, the Applicants were in possession of the arginine concentration data (Exhibit B and Exhibit C) and the arginase activity data (Exhibit D) from the human subject which is presented graphically as FIGs. 21 and 28 in the application as filed, wherein the physiological arginine level in the human subject was reduced to below 10 μ M for at least 3 days. (See also, US 2005/0244398; Example 9A and 12).

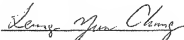
6. We declare that the acts evidenced by Exhibit A, Exhibit B, Exhibit C, and Exhibit D, occurred prior to January 25, 2002.

7. We declare that the subject matter which is described and now claimed in the above-identified application was pursued by the Applicants with due diligence from the acts evidenced by Exhibit A, Exhibit B, Exhibit C, and Exhibit D through to the filing date of the above-identified application.

8. We declare that all statements made herein of our own knowledge are true and that

all statements made on information and belief are believed to be true, and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under §1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

26 Jan 08 
Date Ning Man Cheng

26 Jan 2008 
Date Yun Chung Léung

26 Jan 2008 
Date Wai Hung Lo

Recombinant human arginase in Treatment of Cancer

The day before arginase infusion, two blood samples were taken (before insulin infusion and after insulin infusion). The baseline level of amino acids and the activity of endogenous arginase were measured from these two samples.

Day 1

The first dosage of 50mg pegylated arginase was infused at 10:00 am in Day 1. After the first infusion, blood sample was taken and analyzed with the use of Amino Acid Analyzer at every two hours interval, amino acid profile and activity of arginase were measured

The second dosage of pegylated 50mg arginase was infused at 22:00 p.m. in Day 1 (12 hours after first infusion). Similarly, blood sample was taken and analyzed at every two hours after infusion.

Day 2

The third dosage of pegylated 50mg arginase was infused at 10:00 am in Day 2 (12 hours after second infusion). Blood sample was taken and analyzed at every four hours after infusion.

Day 2 – Day 7

Starting from 13:00 p.m. in Day 2 (3 hours after the third infusion), continuous infusion of 100mg/day arginase was used instead of infusion. Blood sample was taken and analyzed at every four hours after infusion. The continuous infusion was maintained until 13:00 p.m. in Day 7. Continuous infusion of 100mg arginase was stopped at 13:00 p.m. in Day 7

Day 7 – Day 10

After stopping arginase infusion, amino acid profile and the activity of the arginase were still monitored by taken blood sample in every 4 hour.

Day 11 –Day 20

One Single blood sample was taken in each day for monitoring the amino acid profile and the activity of arginase.

Day 21–Day 31

One single blood sample was taken every two days for monitoring the amino acid profile and the activity of the arginase.

EXHIBIT A
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Blood Sample collecting Schedule:

AA = amino acid profile analysis

Activity = activity test for arginase

Day before arginase infusion [REDACTED]	Day 1 [REDACTED]
10:00 a.m. (AA & activity) 16:00 p.m. insulin infusion 21:00 p.m. (AA)	06:00 am (AA) 10:00 a.m. first intermittent infusion, 50mg pegylated arginase in 50 ml PBS 11:00 a.m. (AA & activity) 14:00 p.m. (AA) 16:00 p.m. (AA) 18:00 p.m. (AA & activity) 20:00 p.m. (AA) 22:00 p.m. second intermittent infusion, 50mg pegylated arginase in 50 ml PBS 22:00 (AA)

Day 2 [REDACTED]	Day 3 – Day 6 [REDACTED]
00:00 a.m. (AA) 02:00 a.m. (AA & activity) 04:00 a.m. (AA) 06:00 a.m. (AA) 08:00 a.m. (AA) 10:00 a.m. third intermittent infusion, 50mg pegylated arginase in 50 ml PBS 10:00 a.m. (AA & activity) 13:00 p.m. continuous infusion start, 100 mg pegylated arginase / day 14:00 p.m. (AA) 18:00 p.m. (AA & activity) 22:00 p.m. (AA)	(Continuous infusion 100 mg pegylated arginase / day) 02:00 a.m. (AA & activity) 06:00 a.m. (AA) 10:00 a.m. (AA & activity) 14:00 p.m. (AA) 18:00 p.m. (AA & activity) 22:00 p.m. (AA)

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Day 7 [REDACTED]	Day 8- Day 10 [REDACTED]
(Continuous infusion 100 mg pegylated arginase / day) 02:00 a.m. (AA & activity) 06:00 a.m. (AA) 10:00 a.m. (AA & activity) Stop Continuous infusion 14:00 p.m. (AA) 18:00 p.m. (AA & activity) 22:00 p.m. (AA)	02:00 a.m. (AA & activity) 06:00 a.m. (AA) 10:00 a.m. (AA & activity) 14:00 p.m. (AA) 18:00 p.m. (AA & activity) 22:00 p.m. (AA)

Day 11 – Day 20 [REDACTED]	Day 21- Day 31 [REDACTED]
10:00 a.m. (AA & activity)	AA & Activity was monitored in every two day

EXHIBIT A
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Labeling.	Patient Name	Date	Remarks
1	Mrs. A [REDACTED]	[REDACTED] 10:00	Arginine level, baseline
1.1	Mrs. A [REDACTED]	[REDACTED] 10:00	Activity, 30min
1.2	Mrs. A [REDACTED]	[REDACTED] 10:00	Activity, 1hr
1.3	Mrs. A [REDACTED]	[REDACTED] 10:00	Activity, 2hr
2	Mrs. A [REDACTED]	[REDACTED] 21:00	Arginine level
3	Mrs. A [REDACTED]	[REDACTED] 06:00	Arginine level
First infusion 10:00 50mg pegylated arginase in 50 ml PBS			
4	Mrs. A [REDACTED]	[REDACTED] 11:00	Arginine level
4.0	Mrs. A [REDACTED]	[REDACTED] 11:00	Activity, 0mins
4.1	Mrs. A [REDACTED]	[REDACTED] 11:00	Activity, 10mins
4.2	Mrs. A [REDACTED]	[REDACTED] 11:00	Activity, 30mins
4.3	Mrs. A [REDACTED]	[REDACTED] 11:00	Activity, 60mins
5	Mrs. A [REDACTED]	[REDACTED] 14:00	Arginine level
6	Mrs. A [REDACTED]	[REDACTED] 16:00	Arginine level
7	Mrs. A [REDACTED]	[REDACTED] 18:00	Arginine level
7.0	Mrs. A [REDACTED]	[REDACTED] 18:00	Activity, 0mins
7.1	Mrs. A [REDACTED]	[REDACTED] 18:00	Activity, 10mins
7.2	Mrs. A [REDACTED]	[REDACTED] 18:00	Activity, 30mins
7.3	Mrs. A [REDACTED]	[REDACTED] 18:00	Activity, 60mins
Second infusion 22:00 50mg pegylated arginase in 50 ml PBS			
8	Mrs. A [REDACTED]	[REDACTED] 20:00	Arginine level
9	Mrs. A [REDACTED]	[REDACTED] 22:00	Arginine level
10	Mrs. A [REDACTED]	[REDACTED] 00:00	Arginine level
11	Mrs. A [REDACTED]	[REDACTED] 02:00	Arginine level
11.0	Mrs. A [REDACTED]	[REDACTED] 02:00	Activity, 0mins
11.1	Mrs. A [REDACTED]	[REDACTED] 02:00	Activity, 10mins
11.2	Mrs. A [REDACTED]	[REDACTED] 02:00	Activity, 30mins
11.3	Mrs. A [REDACTED]	[REDACTED] 02:00	Activity, 60mins
12	Mrs. A [REDACTED]	[REDACTED] 04:00	Arginine level

EXHIBIT A
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Thursday [REDACTED]

Labeling.	Patient Name	Date	Remarks
13	Mrs. A [REDACTED]	[REDACTED] 06:00	Arginine level
14	Mrs. A [REDACTED]	[REDACTED], 08:00	Arginine level
Third infusion 10:00 50mg pegylated arginase in 50 ml PBS			
15	Mrs. A [REDACTED]	[REDACTED], 10:00	Arginine level
15.0	Mrs. A [REDACTED]	[REDACTED], 10:00	Activity, 0mins
15.1	Mrs. A [REDACTED]	[REDACTED], 10:00	Activity, 10mins
15.2	Mrs. A [REDACTED]	[REDACTED], 10:00	Activity, 30mins
15.3	Mrs. A [REDACTED]	[REDACTED], 10:00	Activity, 60mins
Continuous infusion 100mg/days 13:00			
16	Mrs. A [REDACTED]	[REDACTED], 14:00	Arginine level
17.0	Mrs. A [REDACTED]	[REDACTED], 18:00	Activity, 0mins
17.1	Mrs. A [REDACTED]	[REDACTED], 18:00	Activity, 10mins
17.2	Mrs. A [REDACTED]	[REDACTED], 18:00	Activity, 30mins
17.3	Mrs. A [REDACTED]	[REDACTED], 18:00	Activity, 60mins
18	Mrs. A [REDACTED]	[REDACTED], 22:00	Arginine level
19	Mrs. A [REDACTED]	[REDACTED], 02:00	Arginine level
19.0	Mrs. A [REDACTED]	[REDACTED], 02:00	Activity, 0mins
19.1	Mrs. A [REDACTED]	[REDACTED], 02:00	Activity, 10mins
19.2	Mrs. A [REDACTED]	[REDACTED], 02:00	Activity, 30mins
19.3	Mrs. A [REDACTED]	[REDACTED], 02:00	Activity, 60mins

EXHIBIT A
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Friday [REDACTED]

Labeling.	Patient Name	Date	Remarks
20	Mrs. A [REDACTED]	[REDACTED], 06:00	Arginine level
21	Mrs. A [REDACTED]	[REDACTED], 10:00	Arginine level
21.0	Mrs. A [REDACTED]	[REDACTED], 10:00	Activity, 0mins
21.1	Mrs. A [REDACTED]	[REDACTED], 10:00	Activity, 10mins
21.2	Mrs. A [REDACTED]	[REDACTED], 10:00	Activity, 30mins
21.3	Mrs. A [REDACTED]	[REDACTED], 10:00	Activity, 60mins
22	Mrs. A [REDACTED]	[REDACTED], 14:00	Arginine level
23	Mrs. A [REDACTED]	[REDACTED], 18:00	Arginine level
23.0	Mrs. A [REDACTED]	[REDACTED], 18:00	Activity, 0mins
23.1	Mrs. A [REDACTED]	[REDACTED], 18:00	Activity, 10mins
23.2	Mrs. A [REDACTED]	[REDACTED], 18:00	Activity, 30mins
23.3	Mrs. A [REDACTED]	[REDACTED], 18:00	Activity, 60mins
24	Mrs. A [REDACTED]	[REDACTED], 2200	Arginine level
25	Mrs. A [REDACTED]	[REDACTED], 0200	Arginine level
25.0	Mrs. A [REDACTED]	[REDACTED], 0200	Activity, 0mins
25.1	Mrs. A [REDACTED]	[REDACTED], 0200	Activity, 10mins
25.2	Mrs. A [REDACTED]	[REDACTED], 0200	Activity, 30mins
25.3	Mrs. A [REDACTED]	[REDACTED], 0200	Activity, 60mins

EXHIBIT A
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Saturday [REDACTED]

Labeling.	Patient Name	Date	Remarks
26	Mrs. A [REDACTED]	[REDACTED] 06:00	Arginine level
27	Mrs. A [REDACTED]	[REDACTED] 10:00	Arginine level
28	Mrs. A [REDACTED]	[REDACTED] 14:00	Arginine level
28.0	Mrs. A [REDACTED]	[REDACTED] 14:00	Activity, 0mins
28.1	Mrs. A [REDACTED]	[REDACTED] 14:00	Activity, 10mins
28.2	Mrs. A [REDACTED]	[REDACTED] 14:00	Activity, 30mins
28.3	Mrs. A [REDACTED]	[REDACTED] 14:00	Activity, 60mins
29	Mrs. A [REDACTED]	[REDACTED] 18:00	Arginine level
30	Mrs. A [REDACTED]	[REDACTED] 22:00	Arginine level
30.0	Mrs. A [REDACTED]	[REDACTED] 22:00	Activity, 0mins
30.1	Mrs. A [REDACTED]	[REDACTED] 22:00	Activity, 10mins
30.2	Mrs. A [REDACTED]	[REDACTED] 22:00	Activity, 30mins
30.3	Mrs. A [REDACTED]	[REDACTED] 22:00	Activity, 60mins
31	Mrs. A [REDACTED]	[REDACTED] 02:00	Arginine level
31.0	Mrs. A [REDACTED]	[REDACTED] 02:00	Activity, 0mins
31.1	Mrs. A [REDACTED]	[REDACTED] 02:00	Activity, 10mins
31.2	Mrs. A [REDACTED]	[REDACTED] 02:00	Activity, 30mins
31.3	Mrs. A [REDACTED]	[REDACTED] 02:00	Activity, 60mins

EXHIBIT A
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Sunday [REDACTED]

Labeling.	Patient Name	Date	Remarks
32	Mrs. A [REDACTED]	[REDACTED] 06:00	Arginine level
33	Mrs. A [REDACTED]	[REDACTED] 10:00	Arginine level
33.0	Mrs. A [REDACTED]	[REDACTED] 10:00	Activity, 0mins
33.1	Mrs. A [REDACTED]	[REDACTED] 10:00	Activity, 10mins
33.2	Mrs. A [REDACTED]	[REDACTED] 10:00	Activity, 30mins
33.3	Mrs. A [REDACTED]	[REDACTED] 10:00	Activity, 60mins
34	Mrs. A [REDACTED]	[REDACTED] 14:00	Arginine level
35	Mrs. A [REDACTED]	[REDACTED] 18:00	Arginine level
35.0	Mrs. A [REDACTED]	[REDACTED] 18:00	Activity, 0mins
35.1	Mrs. A [REDACTED]	[REDACTED] 18:00	Activity, 10mins
35.2	Mrs. A [REDACTED]	[REDACTED] 18:00	Activity, 30mins
35.3	Mrs. A [REDACTED]	[REDACTED] 18:00	Activity, 60mins
36	Mrs. A [REDACTED]	[REDACTED] 22:00	Arginine level
37	Mrs. A [REDACTED]	[REDACTED] 02:00	Arginine level
37.0	Mrs. A [REDACTED]	[REDACTED] 02:00	Activity, 0mins
37.1	Mrs. A [REDACTED]	[REDACTED] 02:00	Activity, 10mins
37.2	Mrs. A [REDACTED]	[REDACTED] 02:00	Activity, 30mins
37.3	Mrs. A [REDACTED]	[REDACTED] 02:00	Activity, 60mins

EXHIBIT A
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Monday [REDACTED]

Labeling.	Patient Name	Date	Remarks
38	Mrs. A [REDACTED]	[REDACTED] 06:00	Arginine level
39	Mrs. A [REDACTED]	[REDACTED] 10:00	Arginine level
39.0	Mrs. A [REDACTED]	[REDACTED] 10:00	Activity, 0mins
39.1	Mrs. A [REDACTED]	[REDACTED] 10:00	Activity, 10mins
39.2	Mrs. A [REDACTED]	[REDACTED] 10:00	Activity, 30mins
39.3	Mrs. A [REDACTED]	[REDACTED] 10:00	Activity, 60mins
40	Mrs. A [REDACTED]	[REDACTED] 14:00	Arginine level
41	Mrs. A [REDACTED]	[REDACTED] 18:00	Arginine level
41.0	Mrs. A [REDACTED]	[REDACTED] 18:00	Activity, 0mins
41.1	Mrs. A [REDACTED]	[REDACTED] 18:00	Activity, 10mins
41.2	Mrs. A [REDACTED]	[REDACTED] 18:00	Activity, 30mins
41.3	Mrs. A [REDACTED]	[REDACTED] 18:00	Activity, 60mins
42	Mrs. A [REDACTED]	[REDACTED] 22:00	Arginine level
43	Mrs. A [REDACTED]	[REDACTED] 02:00	Arginine level
43.0	Mrs. A [REDACTED]	[REDACTED] 02:00	Activity, 0mins
43.1	Mrs. A [REDACTED]	[REDACTED] 02:00	Activity, 10mins
43.2	Mrs. A [REDACTED]	[REDACTED] 02:00	Activity, 30mins
43.3	Mrs. A [REDACTED]	[REDACTED] 02:00	Activity, 60mins

EXHIBIT A
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Tuesday [REDACTED]

Labeling.	Patient Name	Date	Remarks
44	Mrs. A [REDACTED]	[REDACTED] 06:00	Arginine level
45	Mrs. A [REDACTED]	[REDACTED] 10:00	Arginine level
45.0	Mrs. A [REDACTED]	[REDACTED] 10:00	Activity, 0mins
45.1	Mrs. A [REDACTED]	[REDACTED] 10:00	Activity, 10mins
45.2	Mrs. A [REDACTED]	[REDACTED] 10:00	Activity, 30mins
45.3	Mrs. A [REDACTED]	[REDACTED] 10:00	Activity, 60mins
46	Mrs. A [REDACTED]	[REDACTED] 14:00	Arginine level
47	Mrs. A [REDACTED]	[REDACTED] 18:00	Arginine level
47.0	Mrs. A [REDACTED]	[REDACTED] 18:00	Activity, 0mins
47.1	Mrs. A [REDACTED]	[REDACTED] 18:00	Activity, 10mins
47.2	Mrs. A [REDACTED]	[REDACTED] 18:00	Activity, 30mins
47.3	Mrs. A [REDACTED]	[REDACTED] 18:00	Activity, 60mins
48	Mrs. A [REDACTED]	[REDACTED] 22:00	Arginine level
49	Mrs. A [REDACTED]	[REDACTED] 02:00	Arginine level
49.0	Mrs. A [REDACTED]	[REDACTED] 02:00	Activity, 0mins
49.1	Mrs. A [REDACTED]	[REDACTED] 02:00	Activity, 10mins
49.2	Mrs. A [REDACTED]	[REDACTED] 02:00	Activity, 30mins
49.3	Mrs. A [REDACTED]	[REDACTED] 02:00	Activity, 60mins

EXHIBIT A
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Wednesday [REDACTED]

Labeling.	Patient Name	Date	Remarks
50	Mrs. A [REDACTED]	[REDACTED] 06:00	Arginine level
51	Mrs. A [REDACTED]	[REDACTED] 10:00	Arginine level
51.0	Mrs. A [REDACTED]	[REDACTED] 10:00	Activity, 0mins
51.1	Mrs. A [REDACTED]	[REDACTED] 10:00	Activity, 10mins
51.2	Mrs. A [REDACTED]	[REDACTED] 10:00	Activity, 30mins
51.3	Mrs. A [REDACTED]	[REDACTED] 10:00	Activity, 60mins
52	Mrs. A [REDACTED]	[REDACTED] 14:00	Arginine level
53	Mrs. A [REDACTED]	[REDACTED] 18:00	Arginine level
53.0	Mrs. A [REDACTED]	[REDACTED] 18:00	Activity, 0mins
53.1	Mrs. A [REDACTED]	[REDACTED] 18:00	Activity, 10mins
53.2	Mrs. A [REDACTED]	[REDACTED] 18:00	Activity, 30mins
53.3	Mrs. A [REDACTED]	[REDACTED] 18:00	Activity, 60mins
54	Mrs. A [REDACTED]	[REDACTED] 22:00	Arginine level
54.0	Mrs. A [REDACTED]	[REDACTED] 22:00	Activity, 0mins
54.1	Mrs. A [REDACTED]	[REDACTED] 22:00	Activity, 10mins
54.2	Mrs. A [REDACTED]	[REDACTED] 22:00	Activity, 30mins
54.3	Mrs. A [REDACTED]	[REDACTED] 22:00	Activity, 60mins
55	Mrs. A [REDACTED]	[REDACTED] 02:00	Arginine level
55.0	Mrs. A [REDACTED]	[REDACTED] 02:00	Activity, 0mins
55.1	Mrs. A [REDACTED]	[REDACTED] 02:00	Activity, 10mins
55.2	Mrs. A [REDACTED]	[REDACTED] 02:00	Activity, 30mins
55.3	Mrs. A [REDACTED]	[REDACTED] 02:00	Activity, 60mins

EXHIBIT A
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Thursday [REDACTED]

Labeling.	Patient Name	Date	Remarks
56	Mrs. A [REDACTED]	[REDACTED] 06:00	Arginine level
56.0	Mrs. A [REDACTED]	[REDACTED] 06:00	Activity, 0mins
56.1	Mrs. A [REDACTED]	[REDACTED] 06:00	Activity, 10mins
56.2	Mrs. A [REDACTED]	[REDACTED] 06:00	Activity, 30mins
56.3	Mrs. A [REDACTED]	[REDACTED] 06:00	Activity, 60mins
57	Mrs. A [REDACTED]	[REDACTED] 10:00	Arginine level
57.0	Mrs. A [REDACTED]	[REDACTED] 10:00	Activity, 0mins
57.1	Mrs. A [REDACTED]	[REDACTED] 10:00	Activity, 10mins
57.2	Mrs. A [REDACTED]	[REDACTED] 10:00	Activity, 30mins
57.3	Mrs. A [REDACTED]	[REDACTED] 10:00	Activity, 60mins
58	Mrs. A [REDACTED]	[REDACTED] 14:00	Arginine level
58.0	Mrs. A [REDACTED]	[REDACTED] 14:00	Activity, 0mins
58.1	Mrs. A [REDACTED]	[REDACTED] 14:00	Activity, 10mins
58.2	Mrs. A [REDACTED]	[REDACTED] 14:00	Activity, 30mins
58.3	Mrs. A [REDACTED]	[REDACTED] 14:00	Activity, 60mins
59	Mrs. A [REDACTED]	[REDACTED] 18:00	Arginine level
59.0	Mrs. A [REDACTED]	[REDACTED] 18:00	Activity, 0mins
59.1	Mrs. A [REDACTED]	[REDACTED] 18:00	Activity, 10mins
59.2	Mrs. A [REDACTED]	[REDACTED] 18:00	Activity, 30mins
59.3	Mrs. A [REDACTED]	[REDACTED] 18:00	Activity, 60mins
60	Mrs. A [REDACTED]	[REDACTED] 22:00	Arginine level
60.0	Mrs. A [REDACTED]	[REDACTED] 22:00	Activity, 0mins
60.1	Mrs. A [REDACTED]	[REDACTED] 22:00	Activity, 10mins
60.2	Mrs. A [REDACTED]	[REDACTED] 22:00	Activity, 30mins
60.3	Mrs. A [REDACTED]	[REDACTED] 22:00	Activity, 60mins
61	Mrs. A [REDACTED]	[REDACTED] 02:00	Arginine level
61.0	Mrs. A [REDACTED]	[REDACTED] 02:00	Activity, 0mins
61.1	Mrs. A [REDACTED]	[REDACTED] 02:00	Activity, 10mins
61.2	Mrs. A [REDACTED]	[REDACTED] 02:00	Activity, 30mins
61.3	Mrs. A [REDACTED]	[REDACTED] 02:00	Activity, 60mins

EXHIBIT A
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Friday [REDACTED]

Labeling.	Patient Name	Date	Remarks
62	Mrs. A [REDACTED]	[REDACTED] 06:00	Arginine level
62.0	Mrs. A [REDACTED]	[REDACTED] 06:00	Activity, 0mins
62.1	Mrs. A [REDACTED]	[REDACTED] 06:00	Activity, 10mins
62.2	Mrs. A [REDACTED]	[REDACTED] 06:00	Activity, 30mins
62.3	Mrs. A [REDACTED]	[REDACTED] 06:00	Activity, 60mins
63	Mrs. A [REDACTED]	[REDACTED] 10:00	Arginine level
63.0	Mrs. A [REDACTED]	[REDACTED] 10:00	Activity, 0mins
63.1	Mrs. A [REDACTED]	[REDACTED] 10:00	Activity, 10mins
63.2	Mrs. A [REDACTED]	[REDACTED] 10:00	Activity, 30mins
63.3	Mrs. A [REDACTED]	[REDACTED] 10:00	Activity, 60mins
64	Mrs. A [REDACTED]	[REDACTED] 14:00	Arginine level
64.0	Mrs. A [REDACTED]	[REDACTED] 14:00	Activity, 0mins
64.1	Mrs. A [REDACTED]	[REDACTED] 14:00	Activity, 10mins
64.2	Mrs. A [REDACTED]	[REDACTED] 14:00	Activity, 30mins
64.3	Mrs. A [REDACTED]	[REDACTED] 14:00	Activity, 60mins
65	Mrs. A [REDACTED]	[REDACTED] 18:00	Arginine level
65.0	Mrs. A [REDACTED]	[REDACTED] 18:00	Activity, 0mins
65.1	Mrs. A [REDACTED]	[REDACTED] 18:00	Activity, 10mins
65.2	Mrs. A [REDACTED]	[REDACTED] 18:00	Activity, 30mins
65.3	Mrs. A [REDACTED]	[REDACTED] 18:00	Activity, 60mins
66	Mrs. A [REDACTED]	[REDACTED] 22:00	Arginine level
66.0	Mrs. A [REDACTED]	[REDACTED] 22:00	Activity, 0mins
66.1	Mrs. A [REDACTED]	[REDACTED] 22:00	Activity, 10mins
66.2	Mrs. A [REDACTED]	[REDACTED] 22:00	Activity, 30mins
66.3	Mrs. A [REDACTED]	[REDACTED] 22:00	Activity, 60mins

EXHIBIT A
USSN 10/518,223

Saturday [REDACTED]				
Labeling.	Patient Name	Date		Remarks
67	Mrs. A [REDACTED]	[REDACTED]	10:00	Arginine level
67.0	Mrs. A [REDACTED]	[REDACTED]	10:00	Activity, 0mins
67.1	Mrs. A [REDACTED]	[REDACTED]	10:00	Activity, 10mins
67.2	Mrs. A [REDACTED]	[REDACTED]	10:00	Activity, 30mins
67.3	Mrs. A [REDACTED]	[REDACTED]	10:00	Activity, 60mins
Sunday [REDACTED]				
68	Mrs. A [REDACTED]	[REDACTED]	10:00	Arginine level
68.0	Mrs. A [REDACTED]	[REDACTED]	10:00	Activity, 0mins
68.1	Mrs. A [REDACTED]	[REDACTED]	10:00	Activity, 10mins
68.2	Mrs. A [REDACTED]	[REDACTED]	10:00	Activity, 30mins
68.3	Mrs. A [REDACTED]	[REDACTED]	10:00	Activity, 60mins
Monday [REDACTED]				
69	Mrs. A [REDACTED]	[REDACTED]	10:00	Arginine level
69.0	Mrs. A [REDACTED]	[REDACTED]	10:00	Activity, 0mins
69.1	Mrs. A [REDACTED]	[REDACTED]	10:00	Activity, 10mins
69.2	Mrs. A [REDACTED]	[REDACTED]	10:00	Activity, 30mins
69.3	Mrs. A [REDACTED]	[REDACTED]	10:00	Activity, 60mins
70	Mrs. A [REDACTED]	[REDACTED]	18:00	Arginine level
70.0	Mrs. A [REDACTED]	[REDACTED]	18:00	Activity, 0mins
70.1	Mrs. A [REDACTED]	[REDACTED]	18:00	Activity, 10mins
70.2	Mrs. A [REDACTED]	[REDACTED]	18:00	Activity, 30mins
70.3	Mrs. A [REDACTED]	[REDACTED]	18:00	Activity, 60mins
Tuesday [REDACTED]				
71	Mrs. A [REDACTED]	[REDACTED]	10:00	Arginine level
71.0	Mrs. A [REDACTED]	[REDACTED]	10:00	Activity, 0mins
71.1	Mrs. A [REDACTED]	[REDACTED]	10:00	Activity, 10mins
71.2	Mrs. A [REDACTED]	[REDACTED]	10:00	Activity, 30mins
71.3	Mrs. A [REDACTED]	[REDACTED]	10:00	Activity, 60mins

EXHIBIT A
USSN 10/518,223

Wednesday, [REDACTED]			
72	Mrs. A [REDACTED]	[REDACTED] 10:00	Arginine level
72.0	Mrs. A [REDACTED]	[REDACTED] 10:00	Activity, 0mins
72.1	Mrs. A [REDACTED]	[REDACTED] 10:00	Activity, 10mins
72.2	Mrs. A [REDACTED]	[REDACTED] 10:00	Activity, 30mins
72.3	Mrs. A [REDACTED]	[REDACTED] 10:00	Activity, 60mins
Thursday, [REDACTED]			
73	Mrs. A [REDACTED]	[REDACTED] 10:00	Arginine level
73.0	Mrs. A [REDACTED]	[REDACTED] 10:00	Activity, 0mins
73.1	Mrs. A [REDACTED]	[REDACTED] 10:00	Activity, 10mins
73.2	Mrs. A [REDACTED]	[REDACTED] 10:00	Activity, 30mins
73.3	Mrs. A [REDACTED]	[REDACTED] 10:00	Activity, 60mins
Friday, [REDACTED]			
74	Mrs. A [REDACTED]	[REDACTED] 10:00	Arginine level
74.0	Mrs. A [REDACTED]	[REDACTED] 10:00	Activity, 0mins
74.1	Mrs. A [REDACTED]	[REDACTED] 10:00	Activity, 10mins
74.2	Mrs. A [REDACTED]	[REDACTED] 10:00	Activity, 30mins
74.3	Mrs. A [REDACTED]	[REDACTED] 10:00	Activity, 60mins
Saturday, [REDACTED]			
75	Mrs. A [REDACTED]	[REDACTED] 10:00	Arginine level
75.0	Mrs. A [REDACTED]	[REDACTED] 10:00	Activity, 0mins
75.1	Mrs. A [REDACTED]	[REDACTED] 10:00	Activity, 10mins
75.2	Mrs. A [REDACTED]	[REDACTED] 10:00	Activity, 30mins
75.3	Mrs. A [REDACTED]	[REDACTED] 10:00	Activity, 60mins
Sunday, [REDACTED]			
76	Mrs. A [REDACTED]	[REDACTED] 10:00	Arginine level
76.0	Mrs. A [REDACTED]	[REDACTED] 10:00	Activity, 0mins
76.1	Mrs. A [REDACTED]	[REDACTED] 10:00	Activity, 10mins
76.2	Mrs. A [REDACTED]	[REDACTED] 10:00	Activity, 30mins
73.3	Mrs. A [REDACTED]	[REDACTED] 10:00	Activity, 60mins

EXHIBIT A
USSN 10/518,223

Monday, [REDACTED]			
77	Mrs. A [REDACTED]	[REDACTED] 10:00	Arginine level
77.0	Mrs. A [REDACTED]	[REDACTED] 10:00	Activity, 0mins
77.1	Mrs. A [REDACTED]	[REDACTED] 10:00	Activity, 10mins
77.2	Mrs. A [REDACTED]	[REDACTED] 10:00	Activity, 30mins
77.3	Mrs. A [REDACTED]	[REDACTED] 10:00	Activity, 60mins
Wednesday, [REDACTED]			
78	Mrs. A [REDACTED]	[REDACTED] 10:00	Arginine level
78.0	Mrs. A [REDACTED]	[REDACTED] 10:00	Activity, 0mins
78.1	Mrs. A [REDACTED]	[REDACTED] 10:00	Activity, 10mins
78.2	Mrs. A [REDACTED]	[REDACTED] 10:00	Activity, 30mins
78.3	Mrs. A [REDACTED]	[REDACTED] 10:00	Activity, 60mins
Friday, [REDACTED]			
79	Mrs. A [REDACTED]	[REDACTED] 10:00	Arginine level
79.0	Mrs. A [REDACTED]	[REDACTED] 10:00	Activity, 0mins
79.1	Mrs. A [REDACTED]	[REDACTED] 10:00	Activity, 10mins
79.2	Mrs. A [REDACTED]	[REDACTED] 10:00	Activity, 30mins
79.3	Mrs. A [REDACTED]	[REDACTED] 10:00	Activity, 60mins
Monday [REDACTED]			
80	Mrs. A [REDACTED]	[REDACTED] 10:00	Arginine level
80.0	Mrs. A [REDACTED]	[REDACTED] 10:00	Activity, 0mins
80.1	Mrs. A [REDACTED]	[REDACTED] 10:00	Activity, 10mins
80.2	Mrs. A [REDACTED]	[REDACTED] 10:00	Activity, 30mins
80.3	Mrs. A [REDACTED]	[REDACTED] 10:00	Activity, 60mins
Wednesday [REDACTED]			
81	Mrs. A [REDACTED]	[REDACTED] 10:00	Arginine level
81.0	Mrs. A [REDACTED]	[REDACTED] 10:00	Activity, 0mins
81.1	Mrs. A [REDACTED]	[REDACTED] 10:00	Activity, 10mins
81.2	Mrs. A [REDACTED]	[REDACTED] 10:00	Activity, 30mins
81.3	Mrs. A [REDACTED]	[REDACTED] 10:00	Activity, 60mins

EXHIBIT B
USSN 10/518,223

L-8800 ASM: PR

Series: 0013

Report Name: Original

L-8800 AAA System Manager Report

Analyzed: 05:56 PM

Reported: 07:53 PM

Series: 0013

Vial Number: 54

Sample Name: 45.2

Vial Type: UNK

Injection from this vial: 1 of 1

Volume: 20.0 ul

Sample Description: 45.2, activity, 30mins

Chrom Type: AAA Channel : 1

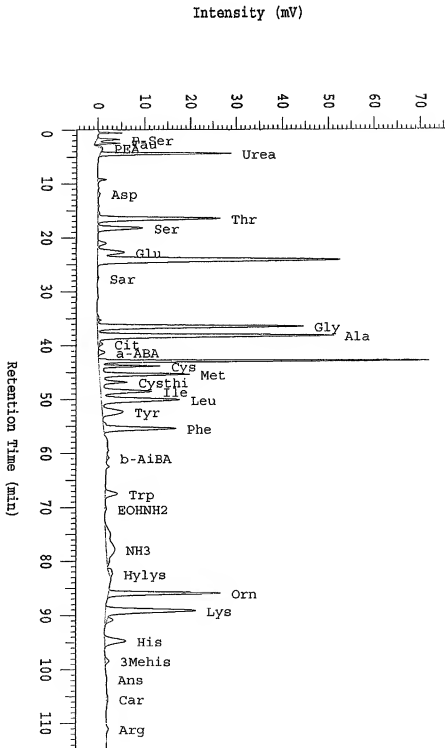


EXHIBIT B
USSN 10/518,223

Peak rejection level: 10000

Page Indicator: 12

L-18800 ASM: PP			Series: 0013			Sample Name: [REDACTED]			Report Name: Original		
Analyzed: [REDACTED]			05:56 PM			Vial Number: 54			Scale Factor 1: 1.000		
Reported: [REDACTED]			07:53 PM			Volume: 20.0 uL			Vial Type: UNK		
No.	RT	Name	Height	Area	Conc 1	Conc 2	Peak Ratio				
					mg/L	ng					
1	1.78	P-Ser	1949	95466	0.167	30.843	0.0				
2	2.48	Tru	5506	85923	0.193	24.104	0.0				
3	3.29	PEA	476	19923	0.056	7.887	0.0				
4	4.42	Urea	28454	577315	55.336	3325.659	0.0				
5	9.19		1933	40660	0.000		0.0				
6	10.75		261	11117	0.000		0.0				
7	11.79	Asp	570	30519	0.055	7.360	0.0				
8	14.05		242	12808	0.000		0.0				
9	15.41		1380	132807	0.000		0.0				
10	16.42	Thr	26582	91897	1.497	178.244	0.0				
11	18.24	Ser	8619	344008	0.566	59.737	0.0				
12	21.05		1822	76844	0.000		0.0				
13	22.75	Glut	5775	290309	0.547	80.519	0.0				
14	24.17		52577	2201585	0.000		0.0				
15	27.52	Sar	254	10330	0.080	7.167	0.0				
16	34.67		398	16499	0.000		0.0				
17	35.21		936	17945	0.000		0.0				
18	36.49	GLY	44715	1408983	2.814	181.457	0.0				
19	38.19	Ala	51252	1763523	2.926	259.432	0.0				
20	41.35	Val	18742	1015715	0.996	7.435	0.0				
21	41.23	α-ABA	1423	58616	0.096	9.860	0.0				
22	42.89		71552	1281031	0.000		0.0				
23	43.81	Cys	13204	260037	0.396	95.063	0.0				
24	45.35	Met	19604	608261	0.349	141.615	0.0				
25	46.79	Cyath	5858	214842	0.274	60.842	0.0				
26	46.52	Ile	11000	450297	0.710	93.178	0.0				
27	50.09	Leu	16976	762310	1.231	161.493	0.0				
28	52.31	Pro	1486	227006	0.206	21.473	0.0				
29	52.31	His	13729	61000	1.051	173.871	0.0				
30	60.87	β-ABA	21620	214670	0.078	8.033	0.0				
31	67.48	TPP	2658	144870	0.000		0.0				
32	70.31	ROH2	354	25655	0.065	3.944	0.0				
33	75.05		1075	122594	0.000		0.0				
34	77.83	NH3	1850	326773	0.618	10.512	0.0				
35	79.93		171	12096	0.000		0.0				
36	82.33	Hylys	791	63931	0.102	16.548	0.0				
37	85.99	Orn	24429	806655	1.356	185.982	0.0				
38	89.19	Lys	15945	962985	0.565	224.609	0.0				
39	92.33		1213	1213	0.000		0.0				
40	94.73	His	4600	281147	0.460	71.340	0.0				
41	98.36	3MetHis	826	46854	0.079	13.289	0.0				
42	101.72	Ans	211	15564	0.110	26.389	0.0				
43	105.45	Car	313	36454	0.180	33.973	0.0				
44	111.00	Arg	433	24059	0.044	7.602	0.0				
			45640	15459550	73.562	5578.097					

EXHIBIT B
USSN 10/518,223

L-8800 ASM: PF

Series: 0013
L-8800-AAA System Manager Report

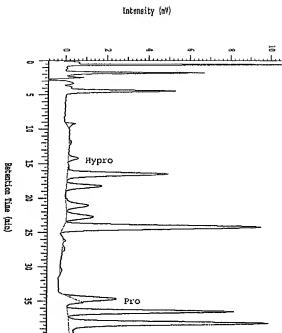
Report Name: original

Analyzed: 05:56 PM

Chrom Type: AAA Channel : 2

Reported: 07:53 PM

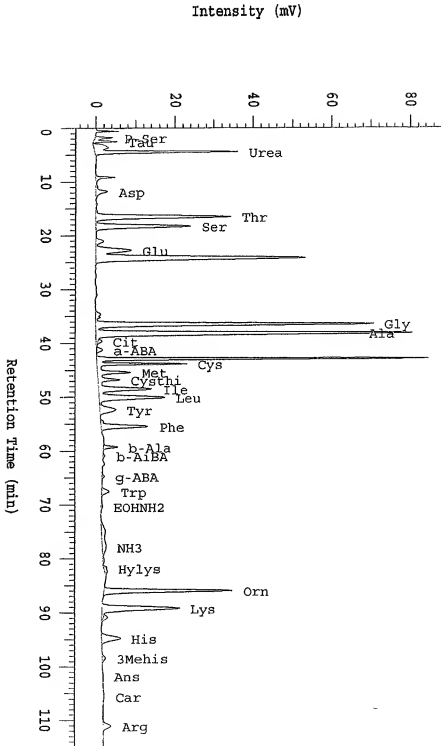
Series: 0013
Vial Number: 54
Vial Type: UNK
Volume: 20.0 uL
Injection from this vial: 1 of 1
Sample Name: 45.2
Sample Description: 45.2, activity, 30mins
Scale Factor 1: 1.000



No.	RT	Name	Height	Area	Conc 1 nmol	Conc 2 ng	Peak Ratio
1	9.20		462	10479	0.000	0.000	0.0
2	14.20		497	15959	0.186	24.447	0.0
3	16.49	Hypro	4871	169603	0.000	0.000	0.0
4	18.24		1727	61889	0.000	0.000	0.0
5	21.03		1102	48560	0.000	0.000	0.0
6	22.65		1311	57965	0.000	0.000	0.0
7	24.19	Pro	9640	384613	0.000	0.000	0.0
8	34.67		2046	76193	0.655	75.420	0.0
9	36.51		8083	245371	0.000	0.000	0.0
10	38.20		9751	353120	0.000	0.000	0.0
			39490	1427752	0.842	95.867	

Peak rejection level: 10000

EXHIBIT B
USSN 10/518,223



L-8800 ASM: PF

Series: 0014

Report Name: original

L-8800 AAA System Manager Report

Analyzed: 09:57 AM

Reported: 11:53 AM

Series: 0014

Vial Number: 62

Sample Name: 49.2

Vial Type: UNK

Injection from this vial: 1 of 1

Volume: 20.0 uL

Chrom Type: AAA Channel : 1

Sample Description:

49.2, 02:00, t30

EXHIBIT B

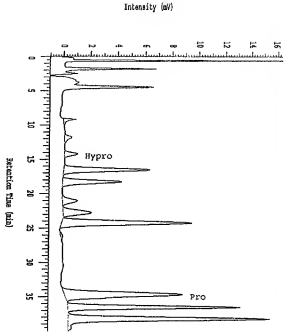
USSN 10/518,223

L-9800 ASM: PF		Series: 0014		Report Name: Original			
Analyzed: [REDACTED]	09:57 AM	Jail Number: 62	Sample Name: [REDACTED]		49.2		
Reported: [REDACTED]	11:53 AM	Volume: 20.0 ul	Vial Type: UNK		Scale Factor 1: 1.000		
No.	RT	Name	Height	Area	Comp 1 mol%	Comp 2 mg	Peak Ratio
1	1.79	P-Ser	4573	91522	0.160	29.568	0.0
2	2.49	Tau	6084	91775	0.206	28.746	0.0
3	3.62	Urea	3720	199524	0.000	0.000	0.0
4	4.43	Urea	36459	176049	73.713	4430.166	0.0
5	5.17	Urea	5021	153294	0.000	0.000	0.0
6	11.79	Asp	3013	152429	0.276	36.760	0.0
7	14.13	Asp	342	18826	0.000	0.000	0.0
8	16.48	Thr	3434	1215392	1.984	236.271	0.0
9	18.24	Ser	24038	881366	1.456	153.048	0.0
10	21.04	Glu	1990	91127	0.000	0.000	0.0
11	22.75	Glu	8979	457429	0.862	126.871	0.0
12	24.17	Glu	53168	2241240	0.000	0.000	0.0
13	34.63	Gly	1275	55207	0.000	0.000	0.0
14	35.19	Gly	7267	233440	0.000	0.000	0.0
15	36.48	Gly	70599	2235727	3.830	287.613	0.0
16	38.16	Ala	80290	2815498	4.575	407.615	0.0
17	39.60	Cit	993	32626	0.056	9.793	0.0
18	41.19	a-ABA	1497	62438	0.102	10.502	0.0
19	42.88	Cys	84322	1511996	0.000	0.000	0.0
20	43.80	Cys	22762	432102	0.657	157.966	0.0
21	45.35	Met	8430	293564	0.458	68.345	0.0
22	46.73	Cyethi	5535	210202	0.268	59.528	0.0
23	46.73	Ileu	14435	542834	0.856	112.265	0.0
24	50.04	Leu	16639	758954	1.225	166.782	0.0
25	52.31	Tyr	4069	270311	0.461	83.461	0.0
26	54.52	Tyr	735	18594	0.000	0.000	0.0
27	55.43	Phe	11847	462460	0.795	131.263	0.0
28	59.27	b-Ala	3592	100893	0.317	28.249	0.0
29	60.87	b-Ala	579	18899	0.069	7.073	0.0
30	64.8	g-ABA	648	27777	0.047	4.801	0.0
31	67.48	Trp	2003	108802	0.000	0.000	0.0
32	70.28	HOHMT	380	29128	0.073	4.478	0.0
33	75.00	HOHMT	129497	129497	0.000	0.000	0.0
34	77.83	NH3	1047	186117	0.314	5.300	0.0
35	80.41	NH3	1987	186117	0.000	0.000	0.0
36	81.75	ByIys	825	28548	0.046	7.390	0.0
37	82.33	ByIys	805	36931	0.000	0.000	0.0
38	85.99	Orn	32615	1090145	1.697	224.314	0.0
39	89.21	Lys	13642	965688	0.562	228.321	0.0
40	90.84	His	1154	52340	0.000	0.000	0.0
41	94.73	His	4740	295496	0.483	74.981	0.0
42	98.39	3Methis	900	52198	0.087	14.805	0.0
43	100.63	Arg	185	11332	0.064	20.231	0.0
44	102.59	Arg	262	23296	0.096	24.111	0.0
45	111.03	Arg	2018	112151	0.203	35.456	0.0
Peak refraction level: 10000			578280	19317398	97.017	7204.697	

EXHIBIT B
USSN 10/518,223

L-6800 ASM: PR
Series: 0014
Report Name: original
Analyzed: 09:57 AM
Chrom Type: AAA Channel : 2
Reported: 11:53 AM

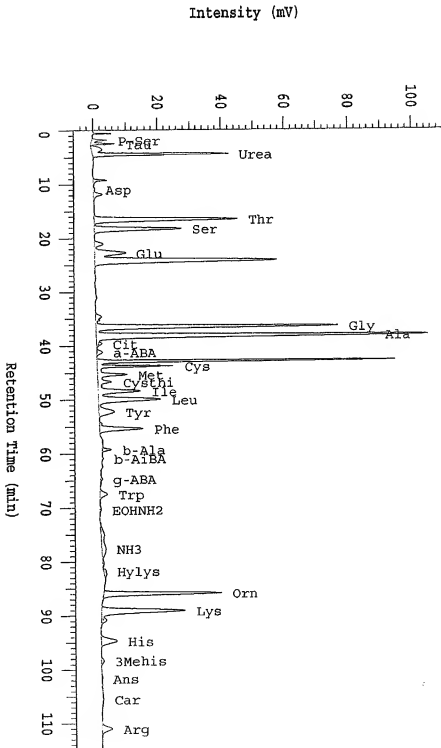
Series: 0014
Vial Number: 62
Vial Type: UNK
Volume: 20.0 uL
Injection from this vial: 1 of 1
Sample Name: 49.2
Sample Description: 49.2, 02:00, t30
Scale Factor 1: 1.000



No.	RT	Name	Height	Area	Conc 1 nmol	Conc 2 ng	Peak Ratio
1	9.17		952	18216	0.000	0.000	0.0
2	11.77		566	25716	0.000	0.000	0.0
3	14.19	Hypro	993	32907	0.384	50.406	0.0
4	16.49		6353	220719	0.000	0.000	0.0
5	18.24		4381	158764	0.000	0.000	0.0
6	21.00		1143	49337	0.000	0.000	0.0
7	22.71		2101	96229	0.000	0.000	0.0
8	24.35		9620	384761	0.000	0.000	0.0
9	26.43	Pro	8757	432842	3.722	428.454	0.0
10	28.46		12832	397636	0.000	0.000	0.0
11	30.17		13061	539866	0.000	0.000	0.0
			62759	2356993	4.107	478.861	

Peak rejection level: 10000

EXHIBIT B
USSN 10/518,223



L-8800 ASM: PF

Series: 0016

Report Name: original

L-8800 AAA System Manager Report

Analyzed: 06:09 PM

Reported: 08:06 PM

Series: 0016

Vial Number: 5

Sample Name: 52.2

Vial Type: UNK

Injection from this vial: 1 of 1

Volume: 20.0 ul

Chrom Type: AAA Channel: 1

Sample Description: 52.2, activity, 30mins

EXHIBIT B
USSN 10/518,223

L-8800 ASN: PF			Series: 0016			Report Name: Original		
Analyzed: 06:09 PM			Vial Number: 5			Sample Name: [REDACTED]		
Reported: [REDACTED]			Volume: 20.0 uL			Vial Type: UWK		
No.	RT	Name	Height	Area	Conc 1 mg/L	Conc 2 mg	Scale Factor 1: 1.000	Peak Ratio
1	1.78	P-Ser	4571	86670	0.151	28.001	0.0	0.0
2	2.48	Tau	7502	107441	0.241	30.141	0.0	0.0
3	3.61	Urea	3266	181169	0.000	0.000	0.0	0.0
4	4.42	Urea	42482	872545	83.633	5026.363	0.0	0.0
5	9.20	Asp	4272	82490	0.000	0.000	0.0	0.0
6	10.33	Asp	16584	116584	0.030	4.024	0.0	0.0
7	11.81	Asp	2639	118710	0.000	0.000	0.0	0.0
8	14.16	Thr	301	15652	0.000	0.000	0.0	0.0
9	16.49	Thr	45047	1571300	2.565	305.459	0.0	0.0
10	18.24	Ser	27172	985414	1.828	171.116	0.0	0.0
11	21.03	Ser	2703	120796	0.000	0.000	0.0	0.0
12	22.72	Glu	9735	496625	0.936	137.742	0.0	0.0
13	24.16	Glu	57265	2404042	0.000	0.000	0.0	0.0
14	34.59		1748	78333	0.000	0.000	0.0	0.0
15	35.20		1110	25192	0.000	0.000	0.0	0.0
16	38.45	GLY	76148	2353728	4.099	307.868	0.0	0.0
17	38.45	Ala	104348	3593438	0.055	521.720	0.0	0.0
18	39.52	Ala	1071	933785	0.053	11.749	0.0	0.0
19	41.12	Cit	1692	69848	0.114	0.000	0.0	0.0
20	42.83	a-Ala	93665	1654060	0.695	0.000	0.0	0.0
21	43.73	Cys	23796	457157	0.000	167.126	0.0	0.0
22	45.27	Met	9336	320177	0.500	74.541	0.0	0.0
23	46.63	Cysch	4414	187730	0.239	53.164	0.0	0.0
24	48.36	Ile	13249	866560	0.861	112.985	0.0	0.0
25	49.32	Leu	19412	866560	1.432	187.815	0.0	0.0
26	52.93	Tyr	35523	355523	0.585	100.601	0.0	0.0
27	54.41	Tyr	4782	93543	0.000	0.000	0.0	0.0
28	55.35	Phe	13537	530427	0.911	150.554	0.0	0.0
29	59.21	Phe	2892	81427	0.256	22.799	0.0	0.0
30	60.81	b-Ala	565	19475	0.071	7.289	0.0	0.0
31	62.39		327	10657	0.000	0.000	0.0	0.0
32	64.63	g-Ala	548	21596	0.036	3.733	0.0	0.0
33	67.43	Tyr	2291	125777	0.000	0.000	0.0	0.0
34	70.28	ECOHMZ	426	29534	0.074	4.541	0.0	0.0
35	72.80		1101	128164	0.000	0.000	0.0	0.0
36	77.51	NH3	1343	208530	0.395	6.719	0.0	0.0
37	80.25		1426	308530	0.000	0.000	0.0	0.0
38	81.69	HyLys	878	30064	0.048	7.782	0.0	0.0
39	82.31		860	40029	0.000	0.000	0.0	0.0
40	85.93	Orn	36958	1231132	1.916	283.324	0.0	0.0
41	89.13	Lys	26093	1270732	2.055	300.444	0.0	0.0
42	90.79		1190	52472	0.000	0.000	0.0	0.0
43	94.65	HIS	5064	313650	0.513	79.587	0.0	0.0
44	96.28	3MeHis	853	45931	0.077	13.027	0.0	0.0
45	105.43	His	180	12678	0.082	19.800	0.0	0.0
46	105.43	His	382	18537	0.037	24.216	0.0	0.0
47	110.95	Arg	3267	18537	0.337	38.638	0.0	0.0
662457			22053017			110.472		
			8203.009					

EXHIBIT B
USSN 10/518,223

L-8800 ASM: EP
Peak rejection level: 10000

Series: 0016

Report Name: original

EXHIBIT B
USSN 10/518,223

L-8800 ASM: PF

Series: 0016

Report Name: original

L-8800 AAA System Manager Report

Analyzed: 06:09 PM

Reported: 08:06 PM

Chrom Type: AAA Channel : 2

Series: 0016

Vial Number: 5

Vial Type: UNK

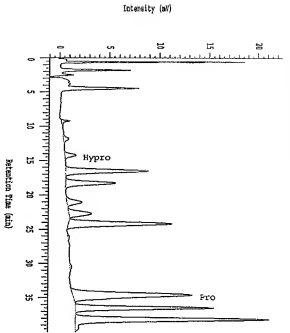
Volume: 20.0 ul

Injection from this vial: 1 of 1

Sample Name: 52.2

Sample Description: 52.2, activity, 30mins

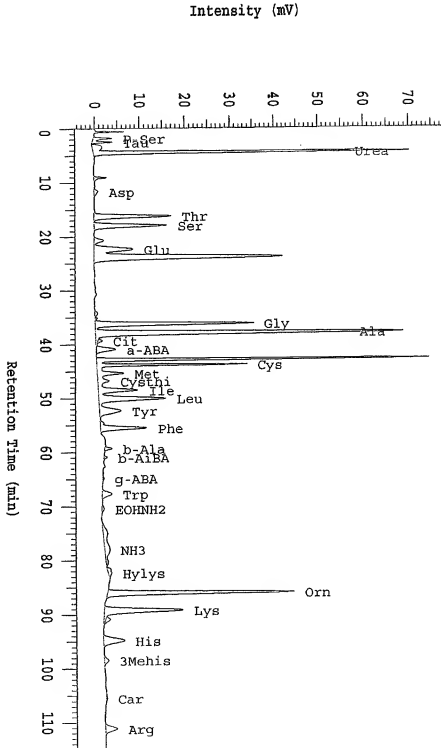
Scale Factor 1: 1.000



No.	RT	Name	Height	Area	Conc 1 mg/ml	Conc 2 mg	Peak Ratio
1	9.21		896	18527	0.000	0.000	0.0
2	11.87		545	27741	0.000	0.000	0.0
3	14.24	Hypro	1138	37480	0.000	57.425	0.0
4	16.51		8284	283627	0.000	0.000	0.0
5	18.24		4994	180539	0.000	0.000	0.0
6	21.03		1540	65456	0.000	0.000	0.0
7	22.71		2292	102907	0.000	0.000	0.0
8	24.16	Pro	10362	412159	0.000	0.000	0.0
9	34.59		11974	590879	5.082	584.889	0.0
10	36.47		13894	428085	0.000	0.000	0.0
11	38.13		15583	693153	0.000	0.000	0.0
			75503	2840632	5.520	642.314	

Peak rejection level: 10000

EXHIBIT B
USSN 10/518,223



L-8800 ASM: PF

Series: 0019

Report Name: original

L-8800 AAA System Manager Report

Analyzed: 02:13 PM

Series: 0019

Sample Name: 67.2

Injection from this vial: 1 of 1

Chrom Type: AAA Channel : 1

Reported: 04:09 PM

Vial Number: 32

Vial Type: UNK

Volume: 20.0 uL

Sample Description: 67.2, 1000, T30

EXHIBIT B
USSN 10/518,223

Peak rejection level: 10000

Page Indicator: 6

L-8800 ASM: PF		Series: 0019		Report Name: Original	
Analyzed: 02:11 PM		il Number: 32		Scale Factor 1. 1.000	
Reported: 04:09 PM		Volume: 20.0 ul		Vial Type: UNK	
No.	RT	Name	Height	Area	Sample Name: Conc 1
					mmol
1	1.79	P-Ser	4154	91634	0.142
2	2.49	Tau	4454	100347	0.147
3	3.57	Urea	2181	127590	0.006
4	4.39	Urea	70506	1506896	144.436
5	9.04		2842	59340	0.006
6	11.59	Asp	937	61642	0.112
7	16.21	Thr	11135	614754	1.003
8	17.93	Ser	16232	600725	0.993
9	20.68	Gln	2183	96163	0.000
10	22.33		456835	456835	0.861
11	23.47		139383	139383	0.000
12	30.67		13932	13932	0.000
13	34.21		706	32855	0.000
14	35.07	Gly	672	12163	0.000
15	36.17	Ala	35411	1142964	1.958
16	37.84	Ala	66648	2457454	3.993
17	39.24	Clf	966	30871	0.053
18	40.84	a-AlA	4287	185576	0.303
19	42.79		74200	1384859	0.000
20	43.79	Cys	3503	615670	0.943
21	44.12	Met	23577	23577	0.139
22	46.73	Cyshti	2575	118314	0.169
23	48.47	Ile	8863	382794	0.604
24	50.04	Ileu	1947	659952	1.130
25	52.28	Tyr	4840	326206	0.556
26	54.57		899	27240	0.000
27	55.51	Phe	10360	412163	0.708
28	59.29	b-AlA	1674	47716	0.150
29	60.52	b-AlA	735	21552	0.078
30	62.73	Met	10784	10784	0.066
31	67.66	Met	2160	129281	0.026
32	70.39	ECOHM2	517	37329	0.094
33	74.89		980	114877	0.000
34	77.93	NH3	1163	178624	0.338
35	80.28		471	34947	0.000
36	82.98	Hylys	808	65380	0.104
37	85.29		44910	44910	1.898
38	89.21	Lys	1574	886417	1.433
39	90.54	Hif	1002	454107	0.000
40	91.13		432	302734	0.455
41	98.39	3MeHls	954	135484	0.000
42	105.40	Car	254	20481	0.084
43	111.08	Avg	2668	154587	0.280
			516813	17242294	163.923
					11122.796
					Peak Ratio

EXHIBIT B
USSN 10/518,223

L-8800 ASM: PF

Series: 0019

Report Name: original

L-8800 - A System Manager Report

Analyzed: 02:13 PM

Reported: 04:09 PM

Chrom Type: AAA Channel : 2

Series: 0019

Vial Number: 32

Vial Type: UNK

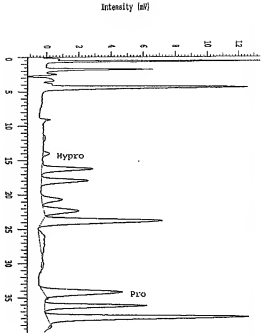
Volume: 20.0 ul

Injection from this vial: 1 of 1

Sample Name: 67.2

Sample Description: 67.2, 1000, t30

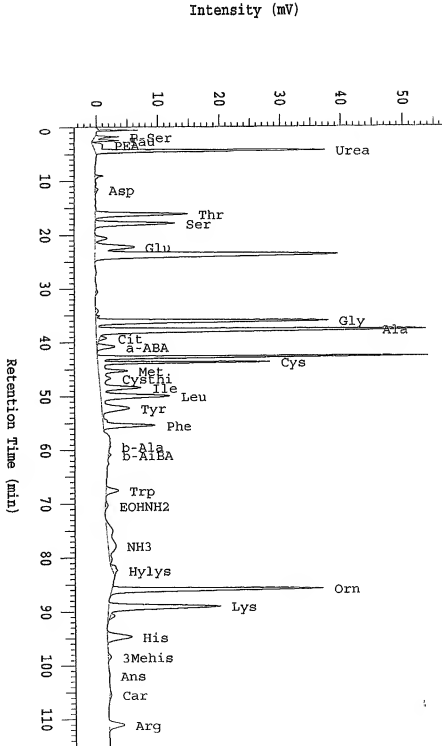
Scale Factor 1: 1.000



No.	RT	Name	Height	Area	Conc 1 nmol	Conc 2 ng	Peak Ratio
1	14.00	Hypox	426	12889	0.151	19.744	0.0
2	15.23		3174	113962	0.000	0.000	0.0
3	17.35		2914	106122	0.000	0.000	0.0
4	20.71		1272	53464	0.000	0.000	0.0
5	23.33		2202	39898	0.000	0.000	0.0
6	25.14		7478	348213	0.000	0.000	0.0
7	26.10		4817	237829	1.354	224.516	0.0
8	36.19	Pro	6368	200373	0.000	0.000	0.0
10	37.85		12670	447512	0.000	0.000	0.0
					2.105	244.660	

Peak rejection level: 10000

EXHIBIT B
USSN 10/518,223



Analyzed: 02:38 PM
Series: 0020
Sample Name: 68-2
Injection from this vial: 1 of 1
Volume: 20.0 ul
Chrom Type: AAA Channel : 1

Reported: 04:34 PM
Vial Number: 42
Vial Type: UNK
Sample Description: 68-2, 10:00

L-8800 AAA System Manager Report

L-8800 ASM: PF

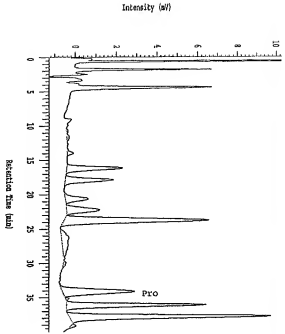
Series: 0020

Report Name: original

EXHIBIT B
USSN 10/518,223

L-8800 ASM: PF
Series: 0020
I-880 AAA System Manager Report
Report Name: original
Analyzed: 02:38 PM
Chrom Type: AAA Channel : 2
Reported: 04:34 PM

Series: 0020
Vial Number: 42
Vial Type: UNK
Volume: 20.0 ul
Injection from this vial: 1 of 1
Sample Name: 68.2
Sample Description: 68.2, 10:00
Scale Factor 1: 1.000



No.	RT	Name	Height	Area	Conc 1 nmol	Conc 2 ng	Peak Ratio
1	16.16		2747	98713	0.000	0.000	0.0
2	17.89		2370	89239	0.000	0.000	0.0
3	20.61		1133	49868	0.000	0.000	0.0
4	22.42		1657	75185	0.000	0.000	0.0
5	23.76		7132	309460	0.000	0.000	0.0
6	26.31	Pro	335	35639	0.000	0.000	0.0
7	34.11		3385	166349	1.431	164.662	0.0
8	34.11		272556	34508	0.000	0.000	0.0
9	37.75		18029	35508	0.000	0.000	0.0
			35946	141997	1.431	164.662	

Peak rejection level: 10000

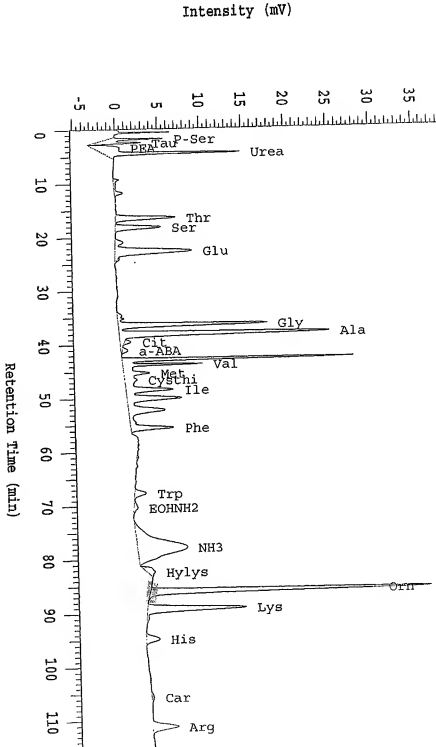
EXHIBIT B
USSN 10/518,223

L-8800 ASM: PF
Channel 1 Noise: 3 uv
Channel 1 Drift: 11 uv

Series: 0020

Report Name: original
Channel 2 Noise: 21 uv
Channel 2 Drift: 9 uv

EXHIBIT B
USSN 10/518,223



L-8800 ASM: PF

Series: 0033

Report Name: original

Activity = 0.0433

L-8800 AAA System Manager Report

Analyzed: 06:33 AM

Reported: 08:30 AM

Series: 0033

Vial Number: 48

Sample Name: 76.2

Sample Description: 76.2, 10:00, t=30

Injection from this vial: 1 of 1

Chrom Type: AAA Channel : 1

EXHIBIT B USSN 10/518,223

L-8800 ASN: PF
 Analyzed: 06:33 AM
 Reported: 08:30 AM
 Series: 0033
 Volume: 48
 Sample Name: 76.2
 Scale Factor 1: 1.000
 Report Name: Original
 Conc 1
 Conc 2
 Peak Ratio

RT	Name	Height	Area	Conc 1	Conc 2	Peak Ratio
1	P-Ser	6551	121038	0.278	51.372	0.0
2	Tau	5666	103396	0.258	35.578	0.0
3	Pha	3133	130438	0.460	64.475	0.0
4	Urea	16211	390587	47.229	2838.480	0.0
5		665	31205	0.000	0.000	0.0
6		920	36995	0.000	0.000	0.0
7	Tar	7097	283588	0.000	0.000	0.0
8	Ser	5379	227738	0.000	0.000	0.0
9	Glu	916	41728	0.000	0.000	0.0
10		528	556816	0.000	0.000	0.0
11		784	2365	0.000	0.000	0.0
12	Gly	17783	640294	1.752	131.584	0.0
13	Ala	25013	1062175	0.000	0.000	0.0
14	Val	824	30612	0.000	0.000	0.0
15	8-HBA	733	33852	0.000	0.000	0.0
16		27518	595952	0.000	0.000	0.0
17	Val	9560	238507	0.544	63.504	0.0
18	Met	3113	14968	0.243	51.178	0.0
19		1522	118462	0.243	47.829	0.0
20	CysH	5674	22488	0.000	83.641	0.0
21	Ile	4844	324681	0.000	0.000	0.0
22		50.04	304262	0.000	0.000	0.0
23		52.25	4711	0.000	0.000	0.0
24	Pha	5107	227082	0.565	93.369	0.0
25	TTP	1371	80636	0.000	0.000	0.0
26	EOHNEZ	478	38630	0.118	6.232	0.0
27		70.36	1211096	4.040	36.037	0.0
28	NH3	5959	88141	0.242	400.656	0.0
29	HyLyS	971	1278632	1.671	242.874	0.0
30		35285	1278632	0.242	50.604	0.0
31	Lys	11719	11651	0.236	55.253	0.0
32	His	1328	39963	0.244	102.135	0.0
33	Arg	2986	197360	0.586		0.0
34		111.19				0.0

Peak rejection level: 10000

EXHIBIT B
USSN 10/518,223

L-8800 ASM: PF

Series: 0033

Report Name: original

L-8800 AA System Manager Report

Analyzed: [REDACTED]

06:33 AM

Reported: [REDACTED]

08:30 AM

Chrom Type: AAA Channel : 2

Series: 0033

Vial Number: 48

Vial Type: UNK

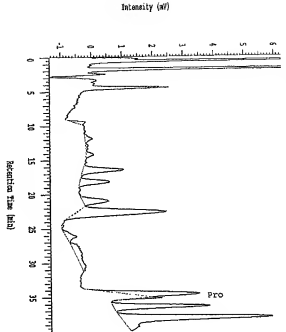
Volume: 20.0 uL

Injection from this vial: 1 of 1

Sample Name: [REDACTED]

Sample Description: [REDACTED]

Scale Factor 1: 1.000



No.	RT	Name	Height	Area	Conc 1 nmol	Conc 2 ng	Peak Ratio
1	11.88		260	10061	0.000	0.000	0.0
2	16.40		1336	55024	0.000	0.000	0.0
3	18.21		986	41763	0.000	0.000	0.0
4	21.00		859	39376	0.000	0.000	0.0
5	22.61		2956	163707	0.000	0.000	0.0
6	26.15		353	19085	0.000	0.000	0.0
7	30.39		175	41895	0.000	0.000	0.0
8	34.63	Pro	2309	92243	0.870	100.159	0.0
9	36.43		3164	109747	0.000	0.000	0.0
10	38.12		5006	234875	0.000	0.000	0.0
			17404	807776	0.870	100.159	

Peak rejection level: 10000

EXHIBIT B
USSN 10/518,223

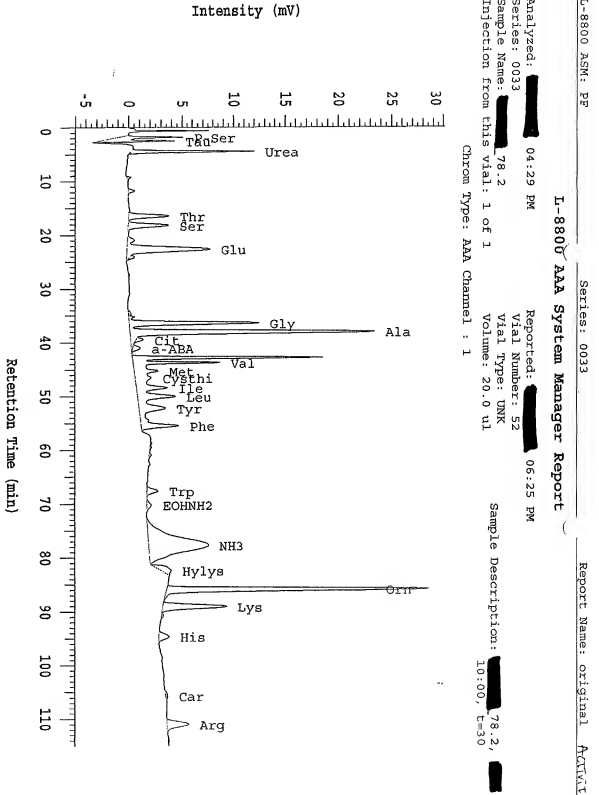


EXHIBIT B USSN 10/518,223

Peak rejection level: 10000

L-8800 ASM: PF		Series: 0033		Report Name: Original			
Analyzed:	04:29 PM	Cal Number:	52	Sample Name:	78.2		
Reported:	06:25 PM	Volume:	20.0 uL	Vial Type:	UNK		
No.	RT	Name	Height	Area	Conc 1 mg/mL	Conc 2 mg	Peak Ratio
1	1.80	P-Ser	6004	115865	0.266	49.177	0.0
2	2.50	Tran	5993	126729	0.342	0.000	0.0
3	4.46	Urea	11822	232427	28.105	1689.086	0.0
4	11.76	Thr	603	20149	0.000	0.000	0.0
5	16.40	Thr	3790	156068	0.000	0.000	0.0
6	18.15	Ser	3766	168284	0.000	0.000	0.0
7	20.89	Glu	651	36752	0.000	0.000	0.0
8	22.60	Glu	7913	483815	0.000	0.000	0.0
9	24.08		442	15626	0.000	0.000	0.0
10	34.63		279	12101	0.000	0.000	0.0
11	35.16		587	14938	0.000	0.000	0.0
12	37.16	GLY	12465	448837	1.228	92.000	0.0
13	38.03	ALA	23224	977864	0.000	0.000	0.0
14	39.40	Cit	672	23548	0.000	0.000	0.0
15	40.97	a-ABA	704	33760	0.000	0.000	0.0
16	42.80		18195	409786	0.000	0.000	0.0
17	43.71	Val	8278	214474	0.489	57.330	0.0
18	45.24	Met	120676	120676	0.276	41.210	0.0
19	46.49	Cyshti	1539	130743	0.237	52.788	0.0
20	48.36	Ile	2894	164955	0.379	49.721	0.0
21	48.36	Ileu	3551	221827	0.539	70.605	0.0
22	52.11	Tyr	2485	202816	0.517	93.605	0.0
23	54.44		797	35602	0.000	0.000	0.0
24	55.45	Phe	3538	163094	0.406	0.000	0.0
25	67.56	TPH	1027	57152	0.000	0.000	0.0
26	70.12	BOHENE2	432	33411	0.102	6.253	0.0
27	77.67	NH3	5697	1157161	3.860	65.617	0.0
28	82.31	HyLys	1036	91209	0.230	37.291	0.0
29	85.93		26954	956405	2.210	300.141	0.0
30	89.08	Lys	6190	327966	0.842	123.150	0.0
31	94.55	His	980	16036	0.188	29.150	0.0
32	105.64	Car	195	14959	0.091	20.697	0.0
33	110.95	Arg	2096	138408	0.411	71.627	0.0
			166043	7373477	40.779	2959.628	

EXHIBIT B
USSN 10/518,223

L-8800 ASM: PF

Series: 0033
L-8800-AA System Manager Report

Report Name: original

Analyzed: 04:29 PM

Reported: 06:25 PM

Chrom Type: AAA Channel : 2

Series: 0033

Vial Number: 52

Vial Type: UNK

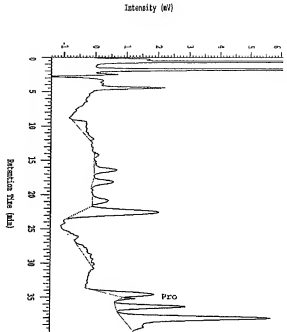
Volume: 20.0 ul

Injection from this vial: 1 of 1

Sample Name: 78.2

Sample Description: 78.2, 10:00, t=30

Scale Factor 1: 1.000



No.	RT	Name	Height	Area	Conc 1 nmol	Conc 2 ng	Peak Ratio
1	11.88		181	38076	0.000	0.000	0.0
2	14.40		744	33472	0.000	0.000	0.0
3	16.42		668	29135	0.000	0.000	0.0
4	21.82		526	24601	0.000	0.000	0.0
5	23.85		2857	145037	0.000	0.000	0.0
6	25.77		483	15458	0.000	0.000	0.0
7	30.12		1376	32787	0.000	0.000	0.0
8	34.60	Pro	1373	30985	0.538	61.876	0.0
9	36.37		2342	75325	0.000	0.000	0.0
10	38.05		4805	228349	0.000	0.000	0.0
				13527	678265	0.538	61.876

Peak rejection level: 10000

EXHIBIT B
USSN 10/518,223

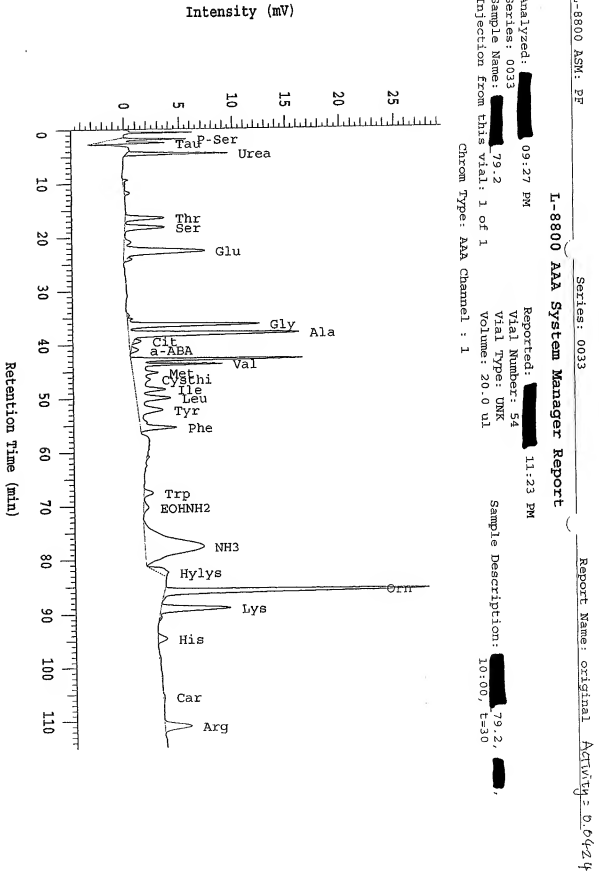


EXHIBIT B
USSN 10/518,223

Peak reflection level: 10000

L-8800 ASM: PF				Series: 0033		Report Name: Original	
Analyzed: [REDACTED]		09:27 PM		Vial Number: 54		Sample Name: [REDACTED]	
Reported: [REDACTED]		11:23 PM		Volume: 20.0 ul		Vial Type: UNK	
No.	RF	Name	Height	Area	Conc 1	Conc 2	Peak Ratio
1	1.79	P-Ser	6489	121314	0.278	51.489	0.0
2	2.49	Tau	115545	0.312	39.008	0.0	0.0
3	4.51	Urea	9321	198088	22.263	1432.000	0.0
4	9.35		550	24594	0.000	0.000	0.0
5	11.84		3834	141649	0.000	0.000	0.0
6	16.17	TPK	3574	155814	0.000	0.000	0.0
7	20.96	Ser	601	31715	0.000	0.000	0.0
8	22.63		7400	450010	0.000	0.000	0.0
9	24.08	Glu	459	16080	0.000	0.000	0.0
10	35.19		514	10623	0.000	0.000	0.0
11	36.37	GLY	12191	434446	1.189	89.281	0.0
12	38.03	CLC	15834	611040	0.000	0.000	0.0
13	39.38		642	31292	0.000	0.000	0.0
14	40.99	a-ABA	4848	31292	0.000	0.000	0.0
15	42.72		15978	363753	0.000	0.000	0.0
16	43.72	Val	8340	221370	0.505	59.173	0.0
17	45.24	Met	2321	116377	0.266	39.742	0.0
18	46.47	Cyschi	1518	128026	0.233	51.691	0.0
19	48.36	Ile	2800	158792	0.365	47.964	0.0
20	49.96	Leu	3138	193388	0.470	61.657	0.0
21	52.15	Tyr	2269	18704	0.455	82.000	0.0
22	54.47		721	14546	0.381	62.978	0.0
23	55.43	Phe	321	150684	0.000	0.000	0.0
24	57.35	PROH2	462	39301	0.120	7.356	0.0
25	77.72		5419	1087680	3.628	61.677	0.0
26	82.41	HYLYZ	979	30796	0.227	37.122	0.0
27	85.93	Lys	26591	542553	2.227	295.794	0.0
28	89.11		6550	347806	0.893	130.600	0.0
29	94.65	His	879	59486	0.169	26.259	0.0
30	95.48	Car	135	42321	0.289	82.000	0.0
31	105.48		2510	166334	0.454	86.074	0.0
32	111.00	Arg					0.0
33							
			151390	6820211	36.436	2728.273	

EXHIBIT B
USSN 10/518,223

L-8800 ASW: PF

Series: 0033

Report Name: original

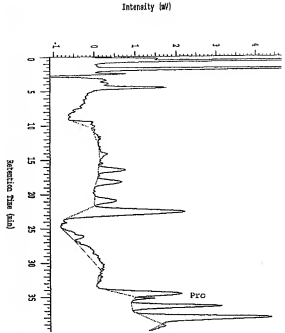
L-8800 AAA System Manager Report

Analyzed: 09:27 PM

Reported: 11:23 PM

Chrom Type: AAA Channel : 2

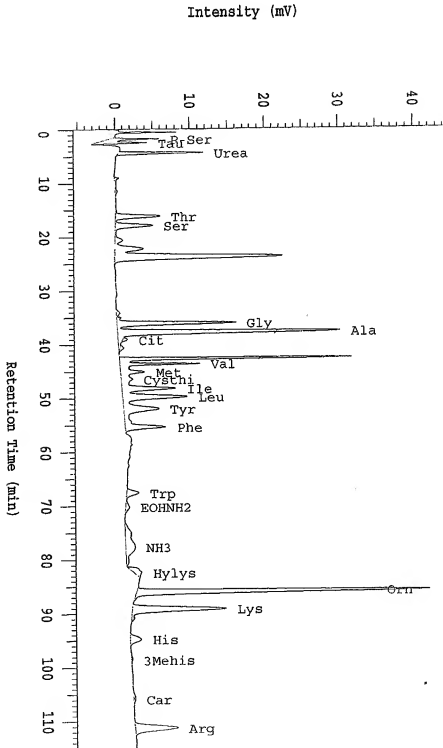
Series: 0033
Vial Number: 54
Vial Type: UNK
Volume: 20.0 uL
Injection from this vial: 1 of 1
Sample Name: 79.2, 79.2, 10:00, t=30
Sample Description:
Scale Factor 1: 1.000



No.	RT	Name	Height	Area	Conc 1 nmol	Conc 2 ng	Peak Ratio
1	10.13		191	17776	0.000	0.000	0.0
2	16.47		673	25853	0.000	0.000	0.0
3	18.19		636	25794	0.000	0.000	0.0
4	20.96		542	24702	0.000	0.000	0.0
5	22.56		2563	143003	0.000	0.000	0.0
6	26.11		350	19429	0.000	0.000	0.0
7	30.23		227	45358	0.000	0.000	0.0
8	34.56	Pro	1473	61933	0.584	67.248	0.0
9	36.37		2232	73775	0.000	0.000	0.0
10	38.04		3146	128070	0.000	0.000	0.0
			12033	565693	0.584	67.248	

Peak rejection level: 10000

EXHIBIT B
USSN 10/518,223



Analyzed: 05:35 PM
Series: 0029
Sample Name: 81.2
Injection from this vial: 1 of 1

Chrom Type: AAA Channel : 1

Reported: 07:32 PM
Vial Number: 23
Vial Type: UNK
Volume: 20.0 ul

Sample Description: 81.2, 1000,
E30(D-2)

L-8800 ASN: PF

Series: 0029

L-8800 AAA System Manager Report

Report Name: Original Activity: 0.076

EXHIBIT B USSN 10/518,223

Peak rejection level: 10000

Page Indicator: 8

L-8800 ASM: PF		Series: 0029		Sample Name: [REDACTED]		Report Name: Original	
Analyzed: [REDACTED]		05:35 PM		al Number: 23		81.2	
Reported: [REDACTED]		07:32 PM		Volume: 20.0 ul		Vial Type: UNK	
No.	RT	Name	Height	Area	Conc 1 mg/L	Conc 2 mg	Scale Factor 1: 1.000
1	1.78	P-Ser	6590	124126	0.285	52.683	129.1
2	2.49	Tau	6317	120628	0.325	40.723	134.2
3	4.39	Urea	11356	217692	26.323	1582.016	104.7
4	9.06		629	26079	0.000	0.000	0.0
5	11.55		296	12486	0.000	0.000	0.0
6	16.16	Thr	5997	240999	0.000	0.000	0.0
7	17.85	Ser	5015	216753	0.000	0.000	0.0
8	20.59		1048	56040	0.000	0.000	0.0
9	22.20		3824	213377	0.000	0.000	0.0
10	23.72		22530	1137804	0.000	0.000	0.0
11	34.42		491	24642	0.000	0.000	0.0
12	34.99		680	12955	0.000	0.000	0.0
13	36.07	GLY	15914	561655	1.537	115.423	100.0
14	37.71	Ala	29566	1210138	0.000	0.000	0.0
15	39.04	Clc	662	21876	0.000	0.000	0.0
16	40.60		551	25938	0.000	0.000	0.0
17	42.65	Val	31259	666272	0.000	0.000	0.0
18	43.63		10669	245616	0.560	65.654	129.3
19	45.08	Met	3270	152452	0.298	46.453	258.4
20	46.41	CysChi	1550	115052	0.298	99.458	109.4
21	48.17	Ile	7192	325952	0.758	142.169	104.7
22	49.75	Leu	8654	446133	1.084	157.976	111.6
23	51.93	Tyr	4747	345239	0.872	121.702	121.5
24	55.35	Phe	5421	295991	0.737	0.000	0.0
25	67.56	TPD	1626	95191	0.000	0.000	0.0
26	70.15	DOHMH2	519	43814	0.134	8.200	143.7
27	75.00		826	94198	0.000	0.000	0.0
28	77.53	NH3	1249	195495	0.652	11.086	84.5
29	80.20		384	22562	0.000	0.000	0.0
30	82.36	HOVS	1066	969310	0.244	39.622	197.0
31	85.36	Urea	12384	140228	1.734	44.212	39.9
32	89.19	His	12540	675929	0.292	253.570	104.3
33	94.73	3-methyl	1485	102681	0.037	6.182	139.4
34	98.55	Car	142	19294	0.118	26.676	163.5
35	105.80	Arg	5702	369721	1.098	191.333	99.4
36	111.24						
250334		10011582		40.860		3522.537	

EXHIBIT B
USSN 10/518,223

L-8800 ASM: PF

Series: 0029
L-8800 AA System Manager Report

Report Name: original

Analyzed: [REDACTED]

05:35 PM

Reported: [REDACTED]

07:32 PM

Chrom Type: AAA Channel : 2

Series: 0029

Vial Number: 23

Vial Type: UNK

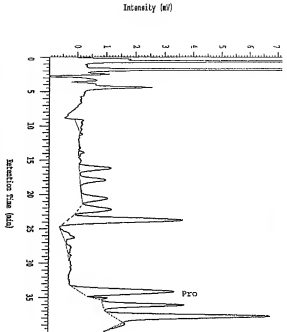
Volume: 20.0 uL

Injection from this vial: 1 of 1

Sample Name: [REDACTED] 81.2

Sample Description: [REDACTED] 81.2, [REDACTED], 1000, t30, D=2

Scale Factor 1: 1.000



No.	RT	Name	Height	Area	Conc 1 mM	Conc 2 mg	Peak Ratio
1	9.15		302	17249	0.000	0.000	0.0
2	15.15		116	43256	0.000	0.000	0.0
3	17.88		804	37340	0.000	0.000	0.0
4	20.53		939	42375	0.000	0.000	0.0
5	22.17		1344	35351	0.000	0.000	0.0
6	23.69		1342	164652	0.000	0.000	0.0
7	26.20		117	2317	0.000	0.000	0.0
8	34.12	Pro	2717	128158	1.491	171.623	93.2
9	36.08		2821	39125	0.000	0.000	0.0
10	37.72		5822	202785	0.000	0.000	0.0
			20360	864503	1.491	171.623	

Peak rejection level: 10000

EXHIBIT C
USSN 10/518,223

Mrs [REDACTED]

Arginine concentration, umol

Sample	Time (hour)	Arginine (umol)
1	-24	44.6
3	-4	23.6
4	1	10.7
6	6	15
8	10	17.6
9	12	20.5
10	14	17.3
13	20	16.5
15	24	12.8
16	28	8.1
17	32	12.1
19	40	8.8
21	44	5
22	52	3.8
23	56	3.1
24	60	4.3
25	64	5.5
26	68	3.2
27	72	2.8
29	80	8.3
30	84	2.6
31	88	5.2
32	92	2.4
34	100	4.5
35	104	3.4
36	108	6.7
37	112	5.9
38	116	8.4
39	120	5.3
40	124	7.5
41	128	5.1
42	132	6.6
43	136	6.3
44	140	5.2
46	148	5.2
47	152	18.5
48	156	33.6
50	164	34.9
51	168	27.8
52	172	39.4
53	176	57

Sample	Time (hour)	Arginine (umol)
54	180	61.3
55	184	49.2
56	188	50.6
57	192	55.1
58	196	61.3
59	200	48.2
60	204	59.1
62	212	44.5
63	216	29.4
64	220	43.2
65	224	33.9
66	228	50.5
67	240	35.1
68	264	27.6
69	288	30.4
70	296	46.8
71	312	53
72	336	46.3
73	360	34.5
75	408	40
76	432	128.5
77	456	124.3
78	504	57.8
79	552	96.7
80	624	82.8
81	672	133.5

EXHIBIT D
USSN 10/518,223

Mrs [REDACTED]
Activity Tests

Sample	Time / hour	Activity / min
4.2	1	0.083
7.2	8	0.036
11.2	16	0.064
15.2	24	0.049
17.2	32	0.093
19.2	40	0.083
21.2	48	0.106
23.2	56	0.133
25.2	64	0.109
28.2	76	0.113
30.2	84	0.096
31.2	88	0.093
33.2	96	0.09
35.2	104	0.107
37.2	112	0.084
39.2	120	0.115
41.2	128	0.135
43.2	136	0.082
* 45.2	144	0.106
* 49.2	160	0.057
51.2	168	0.044
52.2	172	0.046

Sample	Time / hour	Activity / min
53.2	176	0.036
* 56.2	188	0.046
57.2	192	0.05
58.2	196	0.035
59.2	200	0.04
63.2	216	0.0427
64.2	220	0.0429
66.2	228	0.0455
* 67.2	240	0.0404
* 68.2	264	0.042
69.2	288	0.0575
70.2	296	0.05
71.2	312	0.046
72.2	336	0.05
73.2	360	0.05
75.2	408	0.0598
* 76.2	432	0.0433
77.2	456	0.0484
* 78.2	504	0.0446
* 79.2	552	0.0424
80.2	624	0.0408
* 81.2	672	0.0256